8EHQ-1192-13199

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October 6, 1992

8EHQ-92-13199
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CAP

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street., S.W.
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

8ECAP-[ ]

On behalf of the Regulatee and pursuant to Units II B.1.b; II C and II D of the [ ] CAP Agreement, [ ] hereby submits (in triplicate) the attached information. Submission of the information in this letter is made voluntarily under a recently published TSCA §8(e) reporting Q/A, June 1991 TSCA 8(e) Reporting Guide ("Reporting Guide") and is not to be construed as a waiver of due process rights, or as an admission of TSCA violation or that Regulatee's activities with the study compound(s) reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which was not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide" states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due process issues and

3/3/95

clouds the appropriate reporting standard by which regulated persons can assure TSCA §8(e) compliance.

Regulatee is claiming certain bracketed "[ ]" information in this submission as Confidential Business Information and has provided substantiation and a redacted copy for the public file.

For Regulatee,

[

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Attachment 1

Substantiation of Confidential Business Information Claims

CAP Confidentiality Claim: Submitted ID (includes internal codes and personnel).

(4)

Substantiation of Confidential Business Information

1. We request confidentiality for an indefinite period. [ ] in which this chemical was used, and per [ ], this information should not be disclosed.

2..No.

3. Yes. This information was [ ] as part of [ ]. No non-confidential disclosure is [ ].

4. This information is handled by standard procedures for company information labelled [ ] These procedures are outlined in our [ ].

5.The material appears on [ ] but does not appear on any other literature, professional or trade publications, or other media.
The [ ] preclude non-confidential disclosure of this material.

6.No.

7."Submitter does not assert that confidential information claimed as CBI herein is "health and safety data" pursuant to 40 CFR Part 2.306(e)(i). Notwithstanding this claim and the inapplicability of this subpart to the information claimed as CBI, submitter states as follows":

•Disclosure would not reveal
-confidential process information
-Confidential proportions of the mixture.
However, it would reveal information unrelated to the effects of the substance on human health or the environment.

Disclosure [ ] would reveal the [ ] to which the material is put.

(5)

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2 see end of report

CAS #8047-15-~~1~~
Chem: Saponins
Title: Inhalation Approximate Lethal Concentration (ALC)
Date: 10-9-81
Summary of Effects: Highly toxic

Material Tested
Saponins

INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC)

Objective: The purpose of this investigation was to determine the 4-hour inhalation ALC of saponins in male Crl:CD® rats.

Procedure: Except during exposures male Crl:CD® rats were housed in pairs in 8" x 8" x 14" stainless steel cages and provided Purina Certified Rodent Chow® #5002 and water ad libitum. Rats were observed for general suitability for 1 week prior to testing.

Groups of 6 male Crl:CD® rats, 8 weeks old and weighing 225 to 281 grams, were loaded in wire mesh restrainers. They were then exposed head only and for single 4-hour periods to atmospheres containing saponins. During exposure all rats were observed, clinical signs noted, and chamber oxygen content and temperature monitored. Following exposure rats were weighed and observed daily (excluding weekends) for a 14-day observation period.

Generation: Dust atmospheres of saponins were generated with a 3-stage glass generator composed of a dust reservoir, cyclone generator, and elutriator. A stirring rod with plastic paddles agitated the dust in the first 2 stages. Air introduced at the reservoir carried dust particles up to the generator and elutriator. Additional houseline air swept airborne dust from the elutriator stage into the 38 L glass exposure chamber.

Analytical: Chamber atmospheres were analyzed by taking gravimetric samples at 30-minute intervals. Known volumes of atmosphere were drawn through Gelman glass fiber filters (Type AE, 25 mm) at a rate of 1 or 2 liters/minute. The atmospheric concentration of the test material was determined from weight gain of the filters. During 2 exposures the mass median diameter was determined with an 8-stage Sierra cascade impactor.

Results:

Concentration (mg/L)			Mass Median	Fractional Mortality
Mean	S.D.	Range	Diameter (u)	# Deaths/# Exposed
0.16	0.005	0.16 - 0.17	Approx. 4.4	0/6
0.25	0.020	0.21 - 0.27	-	2/6
0.75	0.030	0.72 - 0.81	-	6/6
2.09	1.31	0.98 - 4.1	Approx. 7.6	6/6

Observations:

Exposure: All deaths occurred during exposure with the exception of one rat exposed at 0.75 mg/L that died 48 hours post-exposure. Animals exhibited slight clear to red nasal discharge. Reduced response to sound and labored breathing were noted at 0.75 mg/L. Immediately following exposure to 0.25 mg/L, rats showed poor muscle coordination with clear nasal discharge.

14-Day Observation Period: During the 14-day observation period there was a dose dependent weight loss in all levels. This weight loss ranged from slight to moderate and was followed by normal weight gain.

Summary: The acute inhalation toxicity of saponins to 8-week old male Crl:CD® rats was evaluated in single 4-hour exposures. The approximate lethal concentration was found to be 0.25 mg/L.

During exposure all animals showed slight clear to red nasal discharge, reduced response to sound, and labored breathing. Post-exposure clinical signs were in varying degree, clear to red nasal discharge and poor muscle coordination. This material is considered highly toxic according to Haskell Laboratory Toxicity Classifications.

* Synonym: Saponin (Reagent)

CAS Registry No.: 8047-15-2

Triage of 8(e) Submissions

Date sent to triage: _____ NON-CAP (CAP)

Submission number: 13199A TSCA Inventory: Y N (D)

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

(ATOX) SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: (0) 1 2 **pages** 1,5 **pages** _____

Notes:

Contractor reviewer : JW **Date:** 11/24/96

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1192 - 13199 (5) SEQ. A

TYPE: (INT) SUPP FLWP

SUBMITTER NAME: Confidential

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
(0678) CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER/CUSTOMER
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 10/06/92 OTS DATE: 11/02/92 CSRAD DATE: 03/03/95

CHEMICAL NAME: Saponins

CAS# 8047-15-2

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	YES	YES (DROP/REFER)	RAT	LOW		
CAS SR	NO	NO (CONTINUE)		MED Acute Inhalation Toxicity		
	(INTERIM)	REFER		HIGH		

COMMENTS

13199A

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Acute inhalation toxicity in the male rat is of medium concern based on an approximate lethal concentration of 250 mg/m^3 (0.25 mg/L) following a single 4-hour exposure. Exposure concentrations (mg/m^3) and mortalities were 160 (0/6), 250 (2/6), 750 (6/6), 2090 (6/6). Clinical signs included slight clear to red nasal discharge, slight to moderate dose-dependent weight loss (≥160 mg/m^3), reduced response to sound, labored breathing (750 mg/m^3), and poor muscle coordination (250 mg/m^3).